

Application No.: 10/614,079
Paper Dated: January 12, 2009
In Response to USPTO Correspondence dated August 7, 2008
Attorney Docket No.: 3896-083335 (P-5807)

REMARKS

Claims 1-27 were pending in this application. Claim 1 has been amended to clarify the claimed subject matter. Claims 5, 6, 19, and 20 have been amended for grammatical purposes. Claim 8 has been amended to correct a minor error. Claim 22 has been amended to address the Examiner's indefinite rejection and to clarify the claimed subject matter. New dependent claims 28 and 29 have been added, which contain the limitations of claims 12 and 13, and 26 and 27, respectively. No new subject matter is added by these amendments. No claims have been cancelled. Accordingly, claims 1-29 remain in this application.

35 U.S.C. §112 Rejections

Claims 8 and 22 stand rejected under 35 U.S.C. §112, second paragraph, for indefiniteness. The Examiner asserts that claim 8 contains an insufficient basis for the limitation "data input device." However, claim 1, from which claim 8 depends, sets forth at line 11 a "data input device," which provides proper antecedent basis for the limitation of claim 8. Accordingly, Applicants deem claim 8 to be definite and respectfully request withdrawal of the indefiniteness rejection.

Applicants have amended claim 22 to provide antecedent basis for the "data input device" limitation as well as to clarify the claimed subject matter. Applicants believe that the above amendment to claim 22 overcomes the Examiner's indefiniteness rejections and respectfully request reconsideration of the indefiniteness rejection.

35 U.S.C. §103 Rejections

Claims 1, 6, 9, 10, 12, and 13 stand rejected under 35 U.S.C. §103(a) for obviousness based upon United States Patent No. 5,897,493 to Brown in view of non-patent literature "Hold the Lab in the Palm of Your Hand: Point-of-Care Blood Analyzers Speed Test Results at the Patient's Bedside" by McConnell (hereinafter "the McConnell publication"). Claims 7, 8, 14, 15, 20-24, 26, and 27 stand rejected under 35 U.S.C. §103(a) for obviousness based upon the Brown patent in view of the McConnell publication and further in view of United States Patent Application Publication No. 2003/0140928 to Bui et al. (hereinafter "the Bui

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publication"). Thus, the rejections of independent claims 1 and 14 are based at least upon the Brown patent in view of the McConnell publication. The Bui publication is relied upon for the disclosure of a patient ID label. Its teachings are not relevant to the features of claims 1 and 14 discussed below.

The Brown patent discloses a monitoring system for querying a patient and measuring physiological conditions of the patient and generating a script in response thereto. There is no consideration in the system of Brown for obtaining sample data from a sample testing device that engages a sample cartridge. The McConnell publication is cited to account for those deficiencies. However, contrary to the Examiner's assertion (See bottom of page 3 of the Office Action), the McConnell publication fails to disclose the claim 1 limitation of "controlling said central device to tag said received sample data with a patient identifier label information, said patient identifier label information communicated to said central device via a data input device." The article in the McConnell publication describes a point-of-care blood analyzer having a self-contained sample cartridge (equated by the Examiner to the sample testing device of the claims).

The Abbott Diagnostics advertisement on pages 58-59 of the McConnell publication presents features of a particular point-of-care monitor. The fourth bullet on page 58 lists "Laser-bar-code scanning for all data entry". A bar code scanning feature of that handheld monitor in no way discloses *controlling* a central device to tag the received sample with patient identifier label information. Neither the McConnell article nor the advertisement shown therewith disclose a sample testing device engaging a central device that receives sample data from a sample cartridge that receives cartridge identifier information from the sample testing device and tags received sample data with patient identifier label information communicated to the central device with a data input device. Because at least one of the limitations of claim 1 is not present in the McConnell publication used in forming the obviousness rejections, the obviousness rejections are improper.

The Examiner acknowledges that the Brown patent fails to disclose a sample cartridge as claimed, but relies on the teachings of the McConnell publication to show the existence of an equated "sample cartridge." The Examiner then asserts that the motivation to combine the teachings of the Brown patent with those of the McConnell publication with respect

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to independent claims 1 and 14 is to expedite the collection of sample analysis utilizing a remote system in a patient point of care system / medical environment.

The focus of the presently claimed invention, as indicated in the specification, is to provide for a:

non-contact sample testing environment having wireless data transfer capabilities [that] allows a significant amount of the test equipment to remain beyond the contamination field about a patient. This helps healthcare professionals collect and review data at a patient point of care without the risk of contamination to themselves, or their personal data equipment (See paragraph [0022]).

Although the McConnell publication discusses the benefit of minimized contact with patient blood by utilizing a point-of-care testing device, none of the prior art of record discloses the concept or goal of providing a sample testing environment in which the sample testing device (ordinarily contaminated after use) is not removed from an already contaminated area.

As such, there is no specific motivation provided with respect to why one would want to utilize the sample cartridge device of the McConnell publication in the context of the system of Brown patent. As set forth by the Supreme Court, obviousness rejections must be well-supported and an obviousness analysis “should be made explicit” in that there “must be some articulated reasoning with rational underpinning to support the legal conclusion of obviousness.” A rejection “on obviousness grounds cannot be sustained by mere conclusory statements.” (*KSR v. Teleflex*, 550 U.S. ____ at 14, 127 S. Ct. 1727 (2007), citing *In re Kahn*, 441 F.3d 977 (Fed Cir . 2006)). Thus, the Examiner’s assertion that Brown’s teachings be modified by McConnell’s “to expedite the collection of sample analysis results utilizing a remote system in a patient point of care system” is inaccurate.

Specifically, the system of the Brown patent relates to the *automated acquisition of telemetry data* obtained from devices that are intended to remain with the patient during the course of treatment/observation and are not intended to be portable or be used in a mobile point-of-care context (See column 4, line 61 to column 5, line 6). The device of the McConnell publication relates to the *manual (human) acquisition of biological specimen data*. Replacing the monitoring devices (28) of Brown with the portable devices of McConnell does not expedite sample collection or sample analysis results. Therefore, there would be no motivation to

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combine the teachings of a system in which all operation is automated by virtue of no sample specimen being required to be directly taken by a health care worker with that in which a health care worker's presence is required. In fact, the disclosure of the McConnell publication teaches away from a combination of the references due to the fact the human charged with acquiring biological specimen data is free to enter and exit the contamination field with the point-of-care testing device. There is no disclosure, teaching, or suggestion in any of the cited references regarding the desire to distinguish between analytical devices, testing devices, etc. used within a contamination field and such devices used beyond a contamination field.

New dependent claims 28 and 29 (incorporating the limitations of claims 12 and 13, and 26 and 27, respectively) set forth the relationship between the location of the testing device and that of the central device. Specifically, the testing device is situated within a contamination field (defined as being about a patient at a patient point of care), whereas the central device is situated beyond the contamination field. Contrary to the Examiner's assertion, the McConnell publication fails to disclose the central device beyond a contamination field about a patient. The Examiner points to the first and third bullet on the bottom of page 59 of the McConnell publication for anticipating this aspect. The first bullet refers to docking the testing device with a docking station and the third bullet refers to the uploading of patient tests. None of this disclosure relates to the subject matter of original claims 13 or 27. To the extent that the claimed central device is equated to the overall docked testing device, then the McConnell publication still fails to disclose features of that the testing device being situated beyond the contamination field.

In any case, the Brown and McConnell references, whether considered alone or in combination, fail to disclose, teach, or suggest the location dichotomy with respect to the testing device and central device, as embodied in new claims 28 and 29. As discussed in the specification and referenced above, this location dichotomy is novel and provides advantages over the prior art. Specifically, the issue of overcoming contamination by utilizing point-of-care devices that are not removed from a contaminated area is not disclosed, taught, or suggested by the prior art of record.

In view of the above remarks, Applicants respectfully request reconsideration of the obviousness rejections of independent claims 1 and 14..

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Dependent claims 2-5, 11, 16-19, and 25 stand rejected under 35 U.S.C. §103(a) for obviousness based upon the Brown patent in view of the McConnell publication and further in view of one or more additional cited prior art including United States Application Publication No. 2001/0051766 to Gazdzinski and an I-Stat website (relating to multiple patient testing). These additional references do not account for the failure of the combined teachings of Brown and McConnell, either alone or in combination with Bui, to render obvious the subject matter of claims 1 and 14, nor dependent claims 2-5, 16-19, or 25. Applicants respectfully request that the Examiner also withdraw the obviousness rejections of dependent claims 2-5, 11, 16-19, and 25.

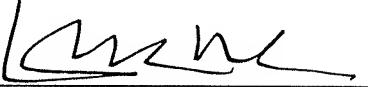
CONCLUSION

Based on the foregoing amendments and remarks, reconsideration of the rejections and allowance of pending claims 1-29 are respectfully requested. Should the Examiner have any questions regarding any of this information, the Examiner is invited to contact Applicants' undersigned representative by telephone at (412) 471-8815.

Respectfully submitted,

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